

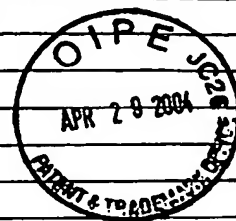
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known			
				Application Number	10/767,824		
				Filing Date	January 29, 2004		
				First Named Inventor	Cooperstone et al		
				Group Art Unit	1614		
Examiner Name	R. Henley						
Attorney Docket Number	AM-101305USA						
Sheet	1	of	3	U.S. PATENT DOCUMENTS			
Examiner Initials*	Cite No. ¹	Document Number <small>Number-Kind Code² (if known)</small>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	A	US-3,929,992	12-30-1975	Sehgal et al			
	B	US-3,993,749	11-23-1976	Sehgal et al			
	C	US-4,401,653	08-30-1983	Chee P. Eng			
	D	US-4,885,171	12-5-1989	Sehgal et al			
	E	US-5,078,999	01-07-1992	Warner et al			
	F	US-5,080,899	01-14-1992	Sturm et al			
	G	US-5,100,899	03-31-1992	Sir R. Calne			
	H	US-5,362,718	11-08-1994	Skotnicki et al			
	I	US-5,321,009	06-14-1994	Baeder et al			
	J	US-5,206,018	04-27-1993	Sehgal et al			
	K	US-5,286,730	02-15-1994	Caufield et al			
	L	US-5,286,731	02-15-1994	Caufield et al			
	M	US-5,288,711	02-22-1994	Mitchell et al			
	N	US-5,387,589	02-07-1995	Prasad S. Kulkarni			
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document <small>Country Code³- Number⁴-Kind Code⁵ (if known)</small>		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	O	EP	0525960	B1	03-20-1996	American Home Products Corporation	
	P	PCT	WO 03/077915	A1	09-25-2003	Wyeth	
	Q	PCT	WO 01/97809	A2	12-27-2001	American Home Products Corporation	
Examiner Signature					Date Considered	1/25/06	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/767,824
				Filing Date	January 29, 2004
				First Named Inventor	Cooperstone et al
				Group Art Unit	1614
				Examiner Name	R. Henley
Sheet	2	of	3	Attorney Docket Number	AM-101305USA



U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	R	US-5,496,832	03-05-1996	Jay J. Armstrong	
	S	US-5,516,781	05-14-1996	Morris et al	
	T	US-5,561,138	10-01-1996	Jay J. Armstrong	
	U	US-6,277,983	08-21-2001	Shaw et al	
	V	US-6,670,355	12-30-2003	Azrolan et al	

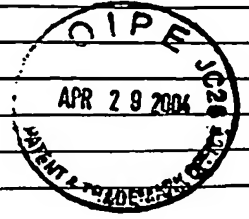
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
Examiner Signature				Date Considered	1/26/05	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete If Known	
		Application Number	10/767,824
		Filing Date	January 29, 2004
		First Named Inventor	Cooperstone et al
		Group Art Unit	1614
		Examiner Name	R. Henley
Sheet 3 of 3	Attorney Docket Number	AM-101305USA	

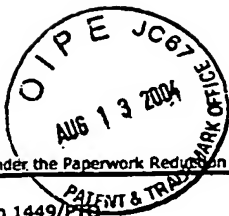


OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), coloumeousse number(s), publisher, city and/or country where published	T ²
<i>[Signature]</i>	W	STARUCH ET AL, FK506 and Rapamycin Inhibit Murine T Cell Activation Through Different Mechanisms, The FASEB Journal, Vol. 3, No. 3 3411, (1989)	
	X	SEHGAL ET AL, Rapamycin (AY-22, 989), A New Antifungal Antibiotic, II. Fermentation, Isolation and Characterization, The Journal of Antibiotics, Vol. XXVIII No. 10, pp. 727-732 (October 1975)	
	Y	VEZINA ET AL, Rapamycin (AY-22,989), A New Antifungal Antibiotic I. Taxonomy of the Producing Streptomycete and Isolation of the Active Principle, The Journal of Antibiotics, Vol. XXVIII No. 10, pp. 721-726 (October 1975)	
	Z	BAKER ET AL, Rapamycin (AY-22,989), A New Antifungal Antibiotic, III. In Vitro and In Vivo Evaluation, The Journal of Antibiotics, Vol. XXXI, No. 6, pp. 539-545, (June 1978)	
	AA	MARTEL ET AL, Inhibition of the Immune Response by Rapamycin, a New Antifungal Antibiotic, Can. J. Physiol. Pharmacol. Vol.55, pp. 48-51 (1977)	
	BB	DUMONT ET AL, Rapamycin Blocks the Immunosuppressive Effect of FK506 But Not That of Cyclosporin A, FASEB JOURNAL, 5256, Vol. 3, No. 4, (1989)	
<i>[Signature]</i>	CC	R. Y. CALNE ET AL, Prolonged Survival of Pig Orthotopic Heart Grafts Treated with Cyclosporin A, Lancet, pp. 1183-1185, (June 3, 1978)	

Examiner Signature	<i>[Signature]</i>	Date Considered	1/25/06
--------------------	--------------------	-----------------	---------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.





PTO/SB/08B (08-03)

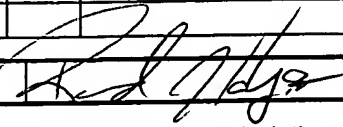
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/767,824		
		Filing Date	January 29, 2004		
		First Named Inventor	Cooperstone		
		Group Art Unit	1614		
		Examiner Name	R. Hensley		
Sheet	1	of	1	Attorney Docket Number	AM-101305USA

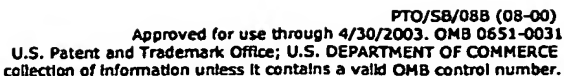
NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	HH	SHIBATA NORIKUNI, <u>Antifibrosis effect of interferongamma (IFNgamma) and rapamycin (Rapa) in immortal human hepatic stellate cells</u> , Database Biosis Online!, 2002, pp. 185-197, Database accession no. PREV200300151275, ISSN: 0386-5924, vol. 28, pp. 185-197, Biosciences Information Service, Kawasaki Igakkai Shi [Abstract]	
	II	S. JAIN, ET AL., <u>Rapamycin Reduces Expression of Fibrosis-Associated Genes in an Experimental Model of Renal Ischaemia Reperfusion Injury</u> , Transplantation Proceedings, February 2001, pp. 556-558, vol. 22, no. 1-2, ISSN: 0041-1345, Elsevier Science, Inc., New York, NY	
	JJ	YOSHIHIDE ARISAKA, <u>Effects of interferon-gamma and rapamycin on transforming growth factor-beta-induced liver fibrosis in an organotypic slice culture</u> , Database Chemabs Online!, 2003, pp. 597-603, Database accession no. 2004:146496, ISSN: 0029-0424, vol. 62(11), Nihon Daigaku Igakkai [Abstract]	
	KK	L. LOPEZ-LAZARRO, ET AL., F. LOKIEC, ET AL., H.C. SWAISLAND, ET AL., U. MAYER, ET AL., L. PLASSWILM, ET AL., G. CARTEI, ET AL., F. LOKIEC, ET AL., M. AIROLDI, ET AL., J. BONI, ET AL., O. TOMOYUKI, ET AL., O. JUAN, ET AL., T. OE, ET AL., <u>Pharmacokinetics poster session (12 individual poster titles)</u> , European Journal of Cancer, October 2001, pp. S66-S69, vol. 37, Pergamon Press, Oxford, GB [Posters]	

Examiner Signature		Date Considered	1/25/06
--------------------	---	-----------------	---------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

* **EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. **DO NOT SEND FEES OR**

